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Application Number	09/981,636
Filing Date	October 16, 2001
First Named Inventor	James D. Marks
Group Art Unit	1648
Examiner Name	Lucas Zachariah
Attorney Docket Number	407T-897710US

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ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Assignment Papers (for an Application)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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<input type="checkbox"/> After Final	<input type="checkbox"/> Petition Routing Slip (PTO/SB/69) and Accompanying Petition	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Status Letter
<input checked="" type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below):
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Tom Hunter, Reg. No. 38,498,	Quine Intellectual Property Law Group P.C.
Signature		
Date	May 10, 2004	

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Atty Docket No: 407T-897710US
Client Ref: 2000-032-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

**JAMES D. MARKS, ULRIK B. NIELSEN, and
DMITRI B. KIRPOTIN**

Application No.: **09/981,636**

Filed: **10/16/2001**

For: **METHODS OF HIGH-THROUGHPUT
SCREENING FOR INTERNALIZING
ANTIBODIES**

Examiner: Lucas Zachariah

Art Unit: 1648

RESPONSE TO RESTRICTION

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is filed in response to the Office Action dated March 9, 2004, containing a Restriction Requirement. The following documents are enclosed herewith:

- 1) A petition to extend the period of response for one month.

REMARKS

In the March 9, 2004 Office Action the Examiner required restriction to one of the following groups under 35 U.S.C. §121:

- Group I: Claims 1-15, drawn to methods for the identification of ligands internalized into a cell;
- Group II: Claims 16-31, and 56-58, drawn to methods of identifying receptors that internalize ligands;
- Group III: Claims 32-43, 54, and 55, drawn to ligand libraries;
- Group IV: Claims 44-53, drawn to constructs comprising a ligand, an effector, and an epitope tag;
- Group V: Claims 59-61, drawn to methods for the identification of ligand internalization modulators;
- Group VI: Claims 62-65, drawn to a metal chelating lipid.
- Group VII: Claims 66-68, drawn to methods for the delivery of an effector into a cell; and
- Group VIII: Claims 69-72, drawn to compositions comprising a lipid, a hydrophilic polymer, and a chelation group, a ligand comprising an epitope tag, and an effector associated with the lipid.

If any of Groups I-V, VII, and VIII is elected, the Examiner required further election between the following Groups:

- A) a peptide ligand
- B) an antibody ligand;
- C) a cytokine ligand; or
- D) a growth factor ligand.

In response to this restriction requirement, Applicants provisionally elect Group I, claims 1-15. With respect to the further election of Groups A, B, C, or D, Applicants provisionally elect group B with traverse.

Applicants note that the restriction between Groups A, B, C, and D is both counter to prevailing law and makes no logical sense.

The Examiner in effect asserts that Applicants are practicing a different method depending on the moiety that is to be screened. Following this logic, if Applicants simultaneously screened two, three or four different ligands (*e.g.* peptide antibody, cytokine and growth factor) simultaneously in the assay of claim 1, then Applicants would in effect be performing four different methods even though they were practicing the same steps with a single pool of ligands. To assert that performing one set of steps would be performing four different methods depending on the constituency of the population of ligands being screened is simply illogical.

Moreover, the Examiner's position is contrary to prevailing law. In making such a restriction, the Examiner effectively requires that a single claim (*e.g.*, claim 1) be divided up and presented in several applications. This flatly contravenes accepted law. As stated by the CCPA:

As a general proposition, an applicant has a right to have *each claim* examined on the merits.

* * *

If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

* * *

§121 provides the Commissioner with the authority to promulgate rules designed to *restrict an application* to one of several claimed inventions, It does not provide a basis under the authority of the Commissioner to *reject a particular claim* on that same basis.

* * *

We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses. *In Re Weber, Soder and Boksay* 198 USPQ 328, 331-332 (CCPA 1978)

See also, In Re Haas 179 USPQ 623, 624, 625 (*In Re Haas I*) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*).

The CCPA thus recognized that an Examiner **may not** reject a particular claim on the basis that it represents “independent and distinct” inventions. *See, In re Weber Soder and Boksay, supra.* Moreover, **the CCPA recognized that imposition of a restriction requirement on a single claim is just such an improper rejection.**

In particular, the courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. §121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I, and In Re Haas II.* More specifically, the CCPA expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *Weber*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- **no matter how broad, which means no matter how many independently patentable inventions may fall within it.** [emphasis added] *In Re Weber* at 334.

Applicants recognize that instead of improperly imposing a restriction requirement on a single claim, the Office may limit initial examination to a “reasonable number” of species encompassed by the claim. *See*, 37 C.F.R. §1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. §112 are complied with. *See, e.g.*, the MPEP at 803.02, *In Re Wolfrum* 179 USPQ 620 (CCPA, 1973) and *In re Kuehl* 177 USPQ 250 (CCPA, 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications that are incapable of capturing the intended scope of the application. It should be clear that the added cost of filing and prosecuting four divisional patent applications in the present case ***does not*** strike an appropriate balance between the administrative concerns of the office and Applicants statutory rights as an inventor.

Finally, Applicants note that the CCPA has explicitly held that improper restriction of a single claim is a decision under the jurisdiction of the Board of Appeals, and the Federal Courts. This is in contrast to simple administrative decisions regarding ordinary restriction requirements,

which are not generally subject to Appellate review. *See, In Re Haas I, supra.* Because restriction of a single claim into multiple groups is tantamount to a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the Board of Appeals and the courts have jurisdiction over the decision. Accordingly, **Applicants expressly reserve the right to appeal any decision that may be made regarding the present petition to the Patent Office Board of Appeals and to the Federal Circuit.**

Applicants further note that if the Examiner's improper restriction to one of Groups A, B, C, or D, is maintained Applicants will never be able to issue, or to even have examined, the full scope of the claimed invention. Claim 1, as filed, is not limited to any particular type of ligand. By improperly reading into this claim the limitation of a peptide ligand, an antibody ligand, a cytokine ligand, or a growth factor ligand, prior to examination, the Examiner denies Applicants the ability to ever have examined claims pertaining to the use of this methods with other ligands. This is clearly improper.

Thus, in view of the foregoing, Applicants submit that the restriction between groups A, B, C, and D is improper and should be withdrawn. Should the Examiner wish to maintain this restriction, **Applicants request a telephone interview with the Examiner, the Examiner's supervisor, and the biotechnology group practice specialist.**

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,



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